IDeA Clinical Research Resource Center (I-CRRC)
PAR-22-150

Ming Lei, PhD
Director, Division for Research Capacity Building

May 18, 2022
Participating NIGMS Staff

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Branch Chief, Research Advancement Programs Branch

**Lisa Dunbar, PhD**  
Section Chief, Scientific Review Branch

**Lumy Sawaki-Adams, MD, PhD**  
Program Director, Research Advancement Programs Branch

**Christy Leake**  
Team Leader, Grants Administration Branch
Building Clinical Research Capacity: A Core Mission of the IDeA Program

- Supporting infrastructure and human resources development to conduct clinical and translational research in IDeA states
- Strengthening IDeA institutions and investigators’ ability to develop competitive clinical and translational research programs
- Enabling clinical and translational research activities that address health conditions prevalent among IDeA state populations.

*Strengthening clinical trial capacity in IDeA states is a pressing need*
Active NIH Clinical Trials in FY21

- Total NIH Supported Trials: $5.6B
- Non-IDeA Trials: $5.2B
- IDeA Trials: $0.4B

Colors indicate the number of studies with locations in that region. Least to Most:
1: Least, 800: Most.
IDeA Clinical Research Resource Center (I-CRRC) to Address Two Key Barriers

➢ Lack of effective communication
  ○ IDeA institutions need to be better informed about ongoing/upcoming clinical trials and complex observational cohort studies and be welcomed to participate
  ○ Trial sponsors need to be better informed about available trial capacities in IDeA institutions so they can include trial sites in IDeA states

➢ Lack of clinical trial workforce, especially clinical research coordinators

Hudson et al, 2005; Friedman et al., 2015; Hamel et al, 2016; Hillyer et al., 2020; Levit et al, 2020; Harrington et al., 2020
I-CRRC: Components, Activities and Award

**A Clinical Trial Service Core** to strengthen communication and develop collaborations between clinical trial sponsors and IDeA institutions.

**A Clinical Research Coordinator Development Program** to develop clinical research coordinators with the knowledge and skills needed to manage clinical trials and complex observational studies in IDeA states.

**An experienced and dedicated team to lead I-CRRC**

NIGMS plans to fund one 5-year award (~ $1.8 million/yr Direct Costs)
Clinical Trial Service Core

- Develop and maintain a trial inventory
- Develop and maintain an IDeA database of clinical expertise, capacities, patient catchment areas, and patient population characteristics of IDeA institutions
- Disseminate information to sponsors, Contract Research Organizations (CROs), and IDeA-state clinical researchers
- Proactively match sponsors/CROs with appropriate IDeA institutions

- Budget: approximately $300,000/yr Direct Costs
  - Costs for trial inventory and IDeA database
  - Costs for activities to match and develop collaborations between sponsors and IDeA Institutions
  - Salary support for personnel
# Clinical Research Coordinator Development Program

<table>
<thead>
<tr>
<th>Participants:</th>
<th>Nurses and/or others involved in clinical care, non-physician health professionals with experience in clinical research and/or its administration</th>
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<tbody>
<tr>
<td><strong>Duration and effort:</strong></td>
<td>Up to two years; 75%</td>
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<tr>
<td><strong>Didactic Component:</strong></td>
<td>Knowledge to manage clinical studies (e.g., policies, billing, participant enrollment, data sharing). Including a syllabus in the application is encouraged</td>
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<tr>
<td><strong>Immersive Component:</strong></td>
<td>Hands-on experience in commuting distance; apply knowledge from didactic component</td>
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<td><strong>CRC Certificate(s):</strong></td>
<td>Minimum of 1 didactic and 1 immersive module</td>
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<tr>
<td><strong>Budget:</strong></td>
<td>~$1.2 M/yr Direct Costs</td>
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<tr>
<td></td>
<td>• Didactic instructor’s effort</td>
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<tr>
<td></td>
<td>• Immersive trial site trainers’ effort</td>
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<td>• Salary support for participants</td>
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I-CRRC: Grantee Institution, Governance, and Administration

- **Grantee Institution**: track record in conducting clinical trials/complex observational studies and related educational activities; experienced personnel and existing resources

- **Governance**: by a steering committee with diverse and balanced representation. *Don’t contact potential members prior to award, or name them in the application*

- **Administration**: led by the PI(s) and key personnel (annual budget: ~ $300,000 DC)
  - PI(s): experienced in leading clinical trials/complex observational studies and programs with multiple stakeholders; knowledgeable about IDeA programs and institutions
  - Salary support for the PI(s) and key personnel
  - Administrative costs such as website development/maintenance and essential travel
Key Dates

• **Letter of Intent Due Date**: August 26, 2022
• **Application Due Date**: September 26, 2022
• **Scientific Review**: March 2023
• **Council Review**: May 2023
• **Earliest Start Date**: July 2023

Read the FOA [PAR-22-150](#) — applications must be responsive and provide specific plans for the required activities
Thank you!

Please Type Questions into the Chat Box

Slides and Video (including the Q & A) will be posted on the I-CRRC Website